

DEC 30 2002

## 510(K) Summary of Substantial Equivalence

Date prepared December 3, 2002

Submitter: Medtronic Ireland  
Parkmore Business Park West  
Galway, Ireland.

Submission Correspondent: Lynn Jensen  
Sr. Regulatory Affairs Specialist  
7000 Central Avenue N.E.  
Minneapolis, MN 55432

Telephone: (763) 514-4459

Fax: (763) 514-6424

E-Mail: lynn.a.jensen@medtronic.com

Proprietary Name: Attain™ 6216A-MP Multi-purpose Guide  
Catheter for Left-heart delivery

Common Name: Catheter, Percutaneous

Device Classification: Class II, 21 CFR § 870.1250

Product Code: 74 DQY

### Performance Standard

Performance standards do not currently exist for these devices. None established under Section 514.

### Device Description

The Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery features one (1) Multi-purpose shaped guide catheter for passing balloon catheters or appropriate leads and one (1) guide catheter dilator to facilitate guide catheter passage.

The Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery contains a dilator that is cleared for market distribution via 510(k).

The key change being made to the catheter is the change in the shape of the distal section in order to respond to the needs of physician preferences and to address subtle anatomical differences between patients. Other changes include the elimination of the existing system components (i.e. adjustable hemostasis valves, guidewires, guidewire clip, guide catheter slitters) which are commercialised with

**CONFIDENTIAL**

May not be reproduced without written permission from Medtronic, Inc.

the Attain™ Access 6218A Left-heart delivery system, with the exception of the guide catheter dilator. The revised configuration of one (1) guide catheter and one (1) guide catheter dilator per package has necessitated changes to the associated packaging and labelling. In addition, the modified device will be given a new model number, Attain™ 6216A-MP.

**Indications for Use**

The intended use of the Medtronic Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery is for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus

**Substantially Equivalent Device**

**Attain LDS 6216A and Attain Access 6218A Left-heart Delivery System Predicate Devices**

<b>Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery</b>	<b>Predicate Device</b>	<b>Predicate Device Manufacturer</b>	<b>Predicate 510(k)</b>
<b>6216A-MP Multi-purpose Guide Catheter</b>	Medtronic Attain LDS 6216A Left-heart Delivery System	Medtronic, Inc. Minneapolis, MN 55432	K021587
	Medtronic Attain Access 6218A Left-heart Delivery System	Medtronic, Inc. Minneapolis, MN 55432	K021589
<b>Guide Catheter Dilator</b>	Medtronic Attain Access 6218A Left-heart Delivery System	Medtronic, Inc. Minneapolis, MN 55432	K021589

**Summary of Studies**

*In vitro* testing, packaging and sterilization validation testing was performed to support substantial equivalence to the predicate devices. The results of this testing indicate that the Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery meets all of its design and performance requirements.

**Biocompatibility Information**

The Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery is biocompatible and meets the requirements of ISO 10993-1. The materials used to fabricate the Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery are identical to those used to fabricate the guide catheters of the predicate devices.

**CONFIDENTIAL**

May not be reproduced without written permission from Medtronic, Inc.

## **Sterilization Validation**

The Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery is sterilized using a 100% Ethylene Oxide (ETO) sterilization process. Appropriate processes for sterilizing the devices were validated.

## **Conclusion (Statement of Equivalence)**

Through the data and information presented, as well as similarities to a legally marketed device, Medtronic, Inc. considers the Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery to be substantially equivalent to the previously discussed legally marketed predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 30 2002

Medtronic, Inc.  
c/o Ms. Lynn Jensen  
Senior Regulatory Affairs Specialist  
Cardiac Rhythm Management  
7000 Central Avenue, N.E.  
Minneapolis, MN 55432

Re: K024032

Trade Name: Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-Heart Delivery  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II (two)  
Product Code: DQY  
Dated: December 3, 2002  
Received: December 6, 2002

Dear Ms. Jensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

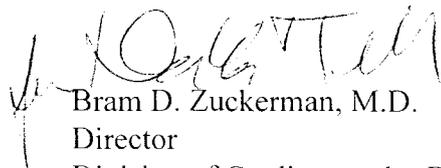
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Ms. Lynn Jensen

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

CONFIDENTIAL

May not be reproduced without written permission from Medtronic, Inc.

## Indications for Use Statement

510(k) Number (if known): N/A

Device Name: Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery

Indications For Use: The Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery is intended for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.

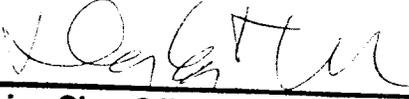
PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number 1K024032